

used to draw electrical power from the handheld device **250** in order to power components (e.g., one or more illumination devices) that are positioned in the housing **260**. Likewise, the headphone jack **400** can be used for data transfer between the handheld device **250** and components in the housing **260**.

[0070] Referring now to FIG. 7A, a target device **500** is illustrated. The target device **500** can be used to normalize/calibrate the response of at least one of the camera or the light source of the handheld device. In one embodiment, the target device may be located on an interior surface **325** of the assay housing **320** in close proximity to the cassette port **270** in an area that is can be illuminated by a light source that will be employed for illumination of an assay cassette and viewable by a camera of a handheld device that is going to be used to capture data from the cassette. For example, the target device may have a known color and/or color intensity that can give a known response for calibrating the light source and the camera. In addition, the target device **500** can be used to ensure that the light source and the camera are directed at the proper point when the handheld device is inserted into the housing.

[0071] Referring now to FIGS. 7A and 7B, the assay housing **320** may further include a mechanical interlocking feature **510** that is positioned and configured to mate with a mechanical interlocking feature **520** on the assay cassette. For example, the mechanical interlocking features **510** and **520** may include tab and cut-out features that are designed to fit together. Such mechanical interlocking features **510** and **520** may be used to ensure that the cassette **105** is inserted in to the assay housing **320** in the proper orientation. In addition, such mechanical interlocking features **510** and **520** may be coupled to a disabling feature that can shut down the device if an incompatible cassette is inserted into the housing **320** or if the cassette is inserted in the wrong orientation. This can, for example, be an important safety feature because it prevents the device from reading the wrong portion of the cassette and giving an erroneous reading as a result.

II. Methods for Detecting at Least One Analyte of Interest in a Sample

[0072] In one embodiment, a method for detecting at least one analyte of interest in a sample is disclosed. The method includes providing a lateral-flow chromatographic assay cassette and providing a testing device that is capable of interfacing with the lateral-flow chromatographic assay cassette.

[0073] In an embodiment, the lateral-flow chromatographic assay cassette may include a capture ligand capable of capturing and localizing at least one analyte of interest in a sample on an analysis surface of the lateral-flow chromatographic assay cassette, at least one reporter configured for interacting with at least one of the analyte of interest or the capture ligand, and at least a first calibration standard and a second calibration standard configured to provide at least a two-point calibration curve. In another embodiment, a lateral-flow chromatographic assay cassette may include an absorbent test strip for analyzing an analyte of interest in an experimental sample and an absorbent calibration strip for running at least one calibration standard positioned in proximity to the absorbent test strip as described in greater detail elsewhere herein.

[0074] In one embodiment, the lateral-flow chromatographic assay cassette may be packaged in a packaging system **600**, as illustrated in FIG. 8. The packaging system **600** includes a sealed package (e.g., a plastic-, foil-, or paper-based package) that can be used for containing, storing, or

transporting the lateral-flow chromatographic assay cassette **610** in a clean and preferably sterile environment. A QR code decal or sticker with relevant cassette information could be applied or printed to the outside of each foil pouch or canister.

[0075] In addition, the packaging system **600** includes a tracking code **630**. In the illustrated embodiment, the tracking code **630** is a QR code, which is a two-dimensional bar code. Two-dimensional bar codes, like QR codes, can be used to store far more information that can be stored in a conventional bar code. For example, a QR code can be used to store up ~4300 alphanumeric characters (i.e., 0-9, A-Z, space, \$, %, *, +, ., /, :, etc.). In one embodiment, the tracking code **630** can be read by the diagnostic testing system prior to initiating a test. The tracking code may be used to store information that is relevant to the test in a format that can be read by the device. For example, the tracking code **630** can be used for recording and then transmitting to the test system the values for the calibration standards used on the lateral-flow chromatographic assay cassette **610**, manufacturer, date of manufacture, lot number for the lateral-flow chromatographic assay cassette **610**, manufacturer, date of manufacture, and sample/results tracking.

[0076] The testing device may include a testing apparatus that is configured to couple the lateral-flow chromatographic assay cassette to the handheld device in proximity to a light source, the light source being capable of transmitting at least one wavelength of light configured to yield a detectable signal from the reporter(s) (e.g., at least one reporter configured for interacting with at least one of the analyte of interest in a test sample and/or a calibration sample, the first calibration standard, and the second calibration standard), and a detector is positioned to capture the detectable signal from the reporter(s).

[0077] The method may further include applying a liquid sample that includes at least one analyte of interest to the lateral-flow chromatographic assay cassette. In some embodiments, applying a liquid sample to the cassette may include applying separate test and calibration samples to separate test and calibration strips. The method may further include inserting the lateral-flow chromatographic assay cassette into the testing device, illuminating the lateral-flow chromatographic assay cassette with the light source of the testing device in order to yield a detectable signal from the reporter(s), and querying an interpretive algorithm for (i) calculating the calibration curve and then (ii) converting the detectable signal from the first reporter to a numerical value related to the presence or amount of the at least one analyte present in a sample.

[0078] In one embodiment, the calibration curve may be calculated based on values from interaction of a first calibration standard and a second calibration standard with calibration standard lines on the cassette. See, e.g., calibration standards lines **150a** and **150b** of FIG. 1. In another embodiment, the calibration curve may be calculated based on (1) observing a blank region of the absorbent calibration strip, and (2) generating a two point calibration curve that includes a value for the interaction of the analyte of interest from the liquid calibration standard with the ligand immobilized on the absorbent calibration strip and a value for the blank region of the absorbent calibration strip. An example of the blank region on a calibration strip **206b** and **306b** is illustrated at **222** and **322** in FIGS. 2A and 3A. Because the calibration strip may not be pure white, the strip may produce a background signal that needs to be subtracted to get a true value for